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Low Energy Reporting May Increase in Intervention Participants Enrolled in Dietary Intervention Trials

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ABSTRACT

Objective To examine differences in low energy intake reporting between intervention and control groups during a dietary intervention trial.

Design Retrospective data analysis from a subcohort of participants in the Polyp Prevention Trial (PPT), a 4-year, multisite, randomized, controlled dietary intervention trial. Intervention consisted of educational material and counseling sessions supporting a low-fat, high-fiber diet. Baseline and annual demographics, behavioral characteristics, energy intake (EI) based on self-reported 4-day food records, and height and weight of participants were collected at baseline and annually. Basal metabolic rate (BMR) was estimated (using the Schofield equation) to calculate EI/BMR.

Subjects Of the 443 participants (302 male, 141 female) at baseline, 195 (43.3%) were younger than 60 years, and 394 (91%) were white. At Year 4, 383 participants remained: 186 (122 men, 64 women) in the intervention group, and 197 (133 men, 64 women) in the control group.

Statistical Analyses Using either paired t tests or analysis of variance, the differences between the means for EI, weight, and EI/BMR were compared at baseline, Year 1, and Year 4 for the participants who remained at Year 4. The Goldberg EI/BMR cutoff value of 1.06 (for plausible EI) identified participants who reported low EI. Linear regression was used to quantify the association of various risk factors to EI/BMR and for multivariate analyses within groups. χ^2

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contingency table analysis quantified differences of low energy reporting within groups.

Results At baseline, 46.8% of women and 11.6% of men reported lower than plausible EI. Only men had a significant increase in low energy reporting after randomization. At Year 1, 18.9% of intervention group men reported low EI compared with 9.8% of control group men ($P<.05$). At Year 4, 23.0% of intervention group men reported low EI compared with 12.8% of control group men ($P<.05$).

Conclusions/Applications Difference in low EI reporting between intervention and control groups could distort results from dietary intervention trials; interpretation of findings from dietary trials must include this potential bias. Intervention study design should include dietary intake data collection methods that are not subject to such bias (ie, biomarkers and performance criteria) to measure intervention compliance.
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Self-reported intake is frequently used in dietary intervention studies to estimate compliance with the intervention and to determine dietary differences between intervention and control groups. Major dietary intervention trials have used food records (subjects record daily all foods consumed); multiple diet recalls (subjects report on foods consumed during the previous 24 hours); and food frequency questionnaires (FFQ) (subjects report food consumption patterns over longer periods of time, from 1 month to 1 year). No widely accepted single standard exists for diet reporting because each method has its reported bias (1,2).

Studies that compare self-reported energy intake (EI) with energy expenditure (measured using doubly labeled water) (3-9) show that self-reported EI is consistently lower than energy expenditure, a phenomenon known as underreporting, or low energy reporting. Low energy reporting may result from several factors: difficulty in reporting or remembering food composition and portion size; changing eating patterns or reported consumption to simplify reporting, to be more socially desirable, or to comply with a prescribed protocol; not reporting on days with high consumption (weekends, parties, etc) or low consumption (dieting or undereating) (8,10); erroneous package labeling on locally produced foods; or not reporting complicated foods (mixed dishes) (11) or small items (bites, tastes).

Most large-scale epidemiologic investigations of energy expenditure use surrogate measures (12) of total energy expenditure, such as a combination of basal metabolic rate (BMR) (estimated using sex- and weight-specific formulas) and self-reported physical activity expenditure. Studies using this method of estimating energy expenditure also show that low energy reporting is common, especially among women (5,13-15), among individuals who are overweight (5,13,16-20), among African Americans compared with whites (21), among younger rather than older adults (21), among smokers (20), and among those wanting to reduce weight (5). In one study (22), the quality and quantity of food intake reported in the 24-hour recall differed in relation to the degree of underreporting. Another study (23) suggested that degree of underreporting increases as recordkeeping is prolonged; both the reported number of foods and the reported nutrients consumed were lower on the fourth day of recordkeeping than on the first day.

Intervention participants in dietary intervention trials are given a specific dietary message and are often asked to self-monitor their intake: Either situation may lead to biased estimates of compliance. In the only dietary intervention study using doubly labeled water, Martin and colleagues (24) examined extent of low energy reporting among women using a low-fat diet to prevent breast cancer. Although no significant differences existed in accuracy of self-reported EI between intervention and control participants, both groups significantly underreported EI. Within strata of energy expenditure and body mass index (BMI), the intervention group reported lower EI than did the control group (24). In assessing dietary intervention for prevention and treatment of diabetes mellitus (25,26), Martin and colleagues also found underreporting of EI in both intervention and control groups. In assessing the effect of dietary fat on insulin resistance, Tapsell and colleagues (27) found greater energy underreporting during the trial than at baseline (using estimated BMR to establish cutoff values for underreporting EI). However, all of these studies had small numbers of subjects and were not designed to test the difference in underreporting between intervention and control participants.

To test the hypothesis that dietary intervention trial participants who are randomly assigned to the intervention group are more likely to report low EI, we analyzed EI data of a subcohort of participants in the Polyp Prevention Trial (PPT) (28). The PPT, although not designed to test differences in underreporting, provided a sufficient sample size to evaluate the degree of difference in energy reporting between intervention and control group participants. We examined prevalence of low energy reporting at baseline, Year 1, and Year 4 to determine if low EI reporting differed over time between study groups or by demographic and health habits categories.

MATERIALS AND METHODS

Population

Data were from the PPT, a large, multisite clinical trial testing a dietary intervention to reduce risk for adenomatous polyp recurrence (28). The Institutional Review Board at each participating site approved the protocol, and patients provided informed consent. The PPT used a computer program to randomly assign 2,079 men and women, aged 35 years or older, to intervention or control groups. Subjects had at least one histologically confirmed large-bowel adenomatous polyp removed during a colonoscopy procedure within the previous 6 months (29). Recruitment from eight clinical centers in the United States started in the spring of 1991 and ended in January 1994. We analyzed coded EI data, which were available for 443 subjects (302 men, 141 women), which was 20% of the 2,079 PPT participants.

After random assignment of participants, the control group received a two-page National Dairy Council *Guide to Good Eating* pamphlet but no other dietary information.

Dietary Intervention

The intervention group received printed dietary instructional materials and counseling by registered dietitians: 19 individual face-to-face sessions in Year 1, bimonthly group sessions in Year 2, and quarterly group sessions in Years 3 and 4. Participants were instructed to consume 20% of energy from fat, 18 g of fiber per 1,000 kcal consumed, and five to eight servings of fruits and vegetables per day, based on their baseline EI. During the 4-year trial, dietetics professionals contacted intervention participants by phone at least once per month to monitor their progress and help resolve any compliance difficulty. During Years 2 through 4, three participatory intervention group campaigns focused on PPT dietary messages. A more complete description of the intervention program is published elsewhere (30).

Data Collection

The staff at clinical centers participating in the PPT administered a baseline Health and Lifestyle Form (questionnaire) to each study participant to assess a variety of demographic, clinical, and behavioral characteristics (29). Similar questionnaires were completed at each annual visit.

The PPT used three measures to assess dietary intake and compliance: (a) a modified Block/National Cancer Institute food frequency questionnaire (31), (b) 4-day food records (4DFR), and (c) 24-hour recall. We analyzed the data from the 4DFR to evaluate the degree of low energy reporting because, of the three methods, 4DFR give the best estimates of EI. All participants (control and intervention) completed 4DFR at baseline and at annual visits at the end of Years 1, 2, 3, and 4.

Intervention and control participants viewed instructional videos demonstrating food portion size estimation with proper 4DFR completion and received this instruction by dietetics professionals who were certified. To ensure that participants understood dietary assessment procedures, completed 4DFRs were reviewed with each participant by staff trained and certified in methods of collecting 24-hour recall information by the Nutrition Coding Center (NCC) of the University of Minnesota. Standardized, probing questions helped to ensure that all foods were reported; the same staff member who reviewed a participant's 4DFR coded that record. For intervention group participants, the reviewing staff member could not be involved with that participant's individual counseling. A randomly selected (stratified by clinical center) 20% sample (n=443) of 4DFR were coded and analyzed, and this sample was used for this report. The Minnesota Nutrient Data System (NDS) (University of Minnesota, v. 2.9, 1996) was used for analysis of dietary data.

All participants' weight and height were measured at baseline, and BMI (weight [kg]/height [m^2]) was calculated. At the annual visit, PPT staff measured each participant's weight using beam balance scales that were calibrated every 6 months; BMI was recalculated with new weight data annually. Stable weight was defined as a Year 1 or Year 4 value that was within 5 lb (2.3 kg) of baseline weight.

Definition of Low Energy Intake Reporting

To identify participants who reported low EI, we used the methodology described by Goldberg and colleagues (32), which derives cutoff limits for plausible EI depending on the sample size and number of days of dietary data. Using this methodology, EI/BMR ratios are calculated with BMR estimated by the Schofield equation (33) and compared with cutoff values for individuals with 4 days of dietary data. These cutoff values were derived to determine, for each person, whether his or her EI could be a valid estimate for a 4-day period "allowing for the known day-to-day and week-to-week variability and without having to postulate any systematic reduction in intake which may have been caused by the measurement procedure" (32; p 574). The cutoff value therefore accounts for decreased intake on any day of report—for reasons such as travel, boredom, or stress. These cutoff values underestimate underreporting by assuming only sedentary activity.

Black (34) proposed new formulas based on level of physical activity. However, the main focus of our analysis is to examine whether assignment to an intervention group affects the degree of low energy reporting. Because activity levels in the intervention group and the control group were similar, level of physical activity was unlikely to confound the relation between group assignment and low energy reporting. Thus, we considered cutoff values provided in the original Goldberg (32) method as adequate for this assessment. Participants with an EI/BMR less than 1.06 (the Goldberg cutoff limit for 95% confidence interval) were considered to be low EI reporting.

Statistical Analyses

Means and standard deviations were calculated for EI, weight, and EI/BMR. Differences between the means for the variables were compared using either paired t tests or analysis of variance. To compare the differences in percent of low EI reporting, χ^2 contingency analysis was used. The associations of interest were between EI, EI/BMR, weight, and percentage of low EI reporting across several demographic and behavioral characteristics, intervention status, and study years (baseline, Year 1, and Year 4). Multivariate linear regression analysis was used to assess the association between EI/BMR and intervention status in Year 1 and Year 4, separately for men and women, while controlling for BMI, race, age, and activity level. Participants who missed an annual visit or for whom data were incomplete were dropped from the analysis. In the PPT, 11% of the intervention participants and 12% of control group participants were lost to follow up. About 4% from each group died, and the others were lost to follow up for various reasons, including serious illness, moving from the clinical center area, and voluntary withdrawal from the trial. No analysis compared those lost to follow up with those remaining in the trial. SAS (v. 8.2, 1999, SAS Institute, Cary, NC) was used to perform all statistical tests.

RESULTS

Demographics and behavioral characteristics of study participants at baseline are shown in Table 1.

Table 1. Baseline demographic, clinical, and behavioral characteristics of participants in Polyp Prevention Trial by sex

Characteristic	Men (n=302)		Women (n=141)	
Race	*n*	%	*n*	%
Non-Hispanic white	277	92	127	90
Nonwhite[a]	25	8	14	10
Age (y)				
≤60	129	43	65	46
>60	173	57	76	54
Moderate and vigorous activity[b] (h/wk)				
<7	104	34	78	55
≥7	198	66	63	45
Smoking				
Never	101	33	70	50
Former	163	54	50	35
Current	38	13	21	15
Alcohol intake (g/d)				
0	118	39	74	52
0.3-5.9	64	21	38	27
>6.0	120	40	29	21
BMI				
<27	137	45	81	57
≥27	165	55	60	43
Supplement use[c] (no./d)				
0	192	64	78	55
1	51	17	28	20
2+	59	20	35	25

[a]Nonwhite category comprises self-reported racial identity of African American/black, Latino/Hispanic, Native American/Alaska Native, Asian, and other.
[b]Moderate activities included general gardening, lawnmowing, walking (3-4 mph), and singles tennis. Vigorous activities included heavy yardwork, sawing wood, jogging, and canoeing.
[c]Supplements included vitamins A, C, E; thiamin; riboflavin; niacin; folate; calcium; iron; and fiber.

At baseline (before any intervention), younger men (defined as those aged 60 years or younger) reported significantly higher EI than did older men ($P<.001$), and women had no significant difference in reported EI by age group (Table 2). Among women, significant differences in reported EI were seen by activity level (more active women reported higher EI, $P<.01$) and by BMI (heavier women reported lower EI, $P<.001$). Nonwhite men tended to report higher EI and nonwhite women tended to report lower EI compared with their same-sex white counterparts, but no significant difference existed, in part because of small sample size.

Baseline EI/BMR did not differ in men by any demographic or behavioral characteristic measured but was significantly lower in younger women ($P<.05$), in less active women ($P<.01$), and in overweight women ($P<.001$). Percentage of low EI reporting differed by BMI in both men ($P<.05$) and women ($P<.001$); heavier individuals consistently underreported EI more often than did lighter individuals. Percentage of low EI reporting also differed significantly by activity level in women ($P<.05$); less active women underreported EI more often than did more active women.

Values (Table 3) and statistical comparisons (Table 4) of mean EI, estimated EI/BMR, weight, and percentage of low EI reporting at baseline, Year 1, and Year 4 are shown for intervention and control groups. At baseline, no significant difference existed for either men or women between intervention and control groups for any of the parameters measured. However, by Year 1 intervention men had significantly lower EI values ($P=.0087$), lower EI/BMR values ($P=.0129$), and a significantly higher percentage of low EI reporting ($P=.0376$) compared with those of control men. Significant decreases in reported EI, in body weight, and in EI/BMR—along with a significantly increased percentage of low EI reporting from baseline to Year 1 in the intervention group—accounted for the differences between the two groups. Most values were statistically unchanged between Year 1 and Year 4: the differences between intervention and control groups thus remained significant at Year 4. The only exception was body weight, which after having decreased in the intervention group between baseline and Year 1, increased significantly in the intervention group from Year 1 to Year 4 ($P=.0237$) and returned nearly to baseline values. No significant difference in weight between intervention and control groups remained at Year 4.

Among women, no significant differences existed between intervention and control groups for any of the measured parameters in Year 1 and Year 4. Among women, EI decreased over time for both intervention and control groups. The decrease in EI over time was significant for the intervention group between baseline and Year 1 ($P=.0476$) and for the control group between baseline and Year 4 ($P=.0471$). In the intervention group, most of the approximately 100-kcal decrease in EI occurred at Year 1 with no further decrease at Year 4, whereas the 100-kcal decrease in EI for the control group occurred incrementally at both Year 1 and Year 4. Body weight decreased in the intervention group at Year 1 and increased toward baseline levels by Year 4, whereas body weight in the control group increased significantly from baseline to Year 1 and stayed almost stable at Year 4.

For women, no difference in EI/BMR existed between intervention and control groups during Years 1 and 4 across any demographic or behavioral strata studied (Table 5). For men, the biggest and most consistent difference between intervention and control groups was seen in the younger men, heavier men, less active men, those who never smoked or who currently smoked, nonwhite men (although cell sizes at Year 4 were too small to reach statistical significance), and those whose weight either was stable or increased 5 or more pounds.

Because weight loss may give the impression that individuals are underreporting EI when they are consuming less energy than they need, we examined results for both genders between study participants who lost weight and participants whose weight remained stable. No effect of weight change status on underreporting of EI was found in the intervention group compared with the control group.

Table 6 examines the effect of intervention or control group status on EI/BMR in both Years 1 and 4 while controlling for demographic and behavioral covariates. No significant difference in EI/BMR existed between

Table 2. Mean reported energy intake, EI/BMR, and percentage low energy reporting (% LER) among study participants at baseline, by demographic and behavioral characteristics (n=443)

	EI[a] in kcal/d		EI/BMR[b]		% LER[c]	
	Men	Women	Men	Women	Men	Women
	← mean± standard deviation →					
Race						
Non-Hispanic white	2,177±498	1,702±455	1.43±0.44	1.14±0.31	11.6	44.1
Nonwhite	2,301±692	1,524±419	1.50±0.32	1.00±0.33	12.0	71.4
Age (y)						
≤60	2,304***±547	1,764±452	1.48±0.34	1.07*±0.27	10.8	52.3
>60	2,100±476	1,616±449	1.41±0.31	1.18±0.35	12.1	42.1
Moderate and vigorous activity level (h/wk)						
<7	2,133±518	1,559**±409	1.41±0.32	1.07**±0.29	12.5	56.4*
≥7	2,216±515	1,840±460	1.45±0.33	1.20±0.33	11.1	34.9
Smoking status						
Never	2,226±559	1,689±452	1.45±0.36	1.13±0.46	14.8	44.3
Former	2,199±489	1,683±447	1.45±0.31	1.14±0.52	8.0	50.0
Current	2,035±501	1,674±493	1.36±0.31	1.11±0.65	18.4	47.6
Alcohol intake (g/d)						
0	2,185±556	1,645±459	1.44±0.35	1.10±0.30	13.6	47.3
0.3-5.9	2,111±536	1,692±497	1.39±0.33	1.15±0.37	15.6	50.0
>6.0	2,230±462	1,777±372	1.47±0.30	1.17±0.68	7.5	41.4
BMI						
<27	2,124±453	1,752*±429	1.48±0.30	1.21***±0.32	6.6*	32.1***
≥27	2,240±560	1,594±473	1.41±0.34	1.02±0.29	15.8	66.7
Supplement use (no./d)						
0	2,156±495	1,636±461	1.42±0.31	1.08±0.31	10.4[d]	53.8
1	2,245±517	1,780±397	1.48±0.30	1.21±0.32	5.9	42.9
2+	2,237±581	1,717±476	1.47±0.39	1.17±0.31	20.3	34.3

[a]EI=energy intake.
[b]BMR=basal metabolic rate.
[c]LER=low energy intake reporting. See Table 1 for additional term definitions.
[d]LER related to supplement use, $P<.05$, using χ^2 analysis.
*Different from next level, $P<.05$ using analysis of variance.
**Different from next level, $P<.01$ using analysis of variance.
***Different from next level, $P<.001$ using analysis of variance.

women in the intervention group and women in the control group in either year. BMI was significantly and inversely related to the EI/BMR for both sexes in both years. In contrast to women, men in the intervention group had lower values of EI/BMR than men in the control group had. For men, EI/BMR increased with increasing activity level at Year 4 only; no such association existed for women. Age was inversely associated with EI/BMR in Year 1 for women and Year 4 for men.

Table 3. Values for mean energy intake, estimated EI/BMR, weight, and percentage of low energy reporting among participants at baseline, Year 1, and Year 4

	Intervention Men			Control Men			Intervention Women			Control Women		
Variable	B	Y1	Y4	B	Y1	Y4	B	Y1	Y4	B	Y1	Y4
EI[a], mean (kcal/d)	2,186	2,011	1,958	2,211	2,173	2,148	1,708	1,594	1,597	1,662	1,607	1,562
EI/BMR[b]	1.43	1.34	1.30	1.46	1.44	1.42	1.15	1.09	1.10	1.10	1.07	1.06
Weight (lb)	191.6	187.1	189.2	189.0	188.7	189.6	154.5	150.5	152.9	154.3	155.8	156.0
% LER[c]	11.5	18.9	23.0	10.5	9.8	12.8	45.3	51.6	48.4	46.9	48.4	51.6

[a]EI=energy intake.
[b]BMR=basal metabolic rate.
[c]LER=low energy reporting.

Table 4. Comparisons (*P* values) of mean energy intake, estimated EI/BMR, weight, and percentage of low energy reporting among study participants at baseline, Year 1, and Year 4

		P Values			
Group comparisons[a]	n	EI[bc]	EI/BMR[bd]	Weight[b]	% LER[ef]
Intervention men					
B vs Y1	139	.0001	.0008	<.0001	.05
B vs Y4	125	<.0001	<.0001	.0112	.05
Y1 vs Y4	122	NS[g]	NS	.0237	NS
Control men					
B vs Y1	146	NS	NS	NS	NS
B vs Y4	135	NS	NS	NS	NS
Y1 vs Y4	133	NS	NS	NS	NS
Intervention men vs control men					
B		NS	NS	NS	NS
Y1		.0087	.0129	NS	.0376
Y4		.0019	.0022	NS	.0334
Intervention women					
B vs Y1	67	.0476	NS	<.0001	NS
B vs Y4	67	NS	NS	NS	NS
Y1 vs Y4	64	NS	NS	.0273	NS
Control women					
B vs Y1	66	NS	NS	.0123	NS
B vs Y4	64	.0471	NS	NS	NS
Y1 vs Y4	64	NS	NS	NS	NS
Intervention women vs control women					
B		NS	NS	NS	NS
Y1		NS	NS	NS	NS
Y4		NS	NS	NS	NS

[a]Comparisons between 2 visits are based on the number of participants who had measurements at both of those visits.
[b]Intervention vs control group comparisons based on *t* tests; comparisons over time calculated using a Student *t* for testing the hypothesis that the difference is zero.
[c]EI=energy intake.
[d]BMR=basal metabolic rate.
[e]Intervention versus control group comparisons based on χ^2 test; comparisons over time calculated using a test of the difference of two correlated proportions.
[f]LER=low energy reporting.
[g]NS=not significant.

DISCUSSION

Mean values for EI/BMR at baseline ranged from 1.32 to 1.48 in men and from 1.00 to 1.21 in women, data indicating that a large proportion of women but not men in this trial were reporting lower than expected EI before initiation of the intervention. The World Health Organization guidelines (35) suggest that the mean daily EI/BMR for men and women engaged in light work is 1.56, and 1.4 is recommended as the lowest habitual value for EI/BMR compatible with a normal lifestyle. However, the range of values found in our study has also been reported in other studies (12). Our baseline data confirm other reports, which suggest that certain subgroups of the population, particularly women (19,21,36) or overweight individuals (8,36), are more likely to underreport EI.

However, the primary purpose of this study was to examine whether being randomized into the intervention group in a dietary intervention trial affects participants' degree of underreporting EI, a result that would introduce bias in data interpretation. Our findings indicate that in the PPT, men, but not women, were more likely to report low EI when randomized into an intervention group.

Underreporting or misreporting the nutrient or food group of interest in an intervention study is considered "adherence" or "compliance" bias (37-39). Few published studies examine the degree of compliance bias in response to dietary intervention. Forster and colleagues (37) reported a high degree of compliance bias with low-sodium diets and high-potassium diets by comparing 1-day food records with change in urine sodium and potassium biomarker values. Buzzard and colleagues (38) compared 4DFR with unannounced 24-hour recalls in a dietary intervention study of postmenopausal women with breast cancer, and found a compliance bias effect in which 4DFR overestimated fat reduction in the low-fat diet intervention group by 41% at 6 months and 25% at 12 months. Among women, even brief dietary intervention can bias responses to FFQ and a food behavior checklist toward compliance with the intervention goal (39).

Social approval or social desirability bias is often associated with dietary reporting. Social approval bias reflects tendency to seek approval (or praise) in testing

Table 5. Comparison of EI/BMR (energy intake/basal metabolic rate) among women and men in intervention and control groups at Year 1 and Year 4, stratified within covariates[a]

	Women				Men			
	Year 1		Year 4		Year 1		Year 4	
	C[b] (n=66)	I[c] (n=67)	C (n=64)	I (n=64)	C (n=146)	I (n=139)	C (n=133)	I (n=122)
Race								
Non-Hispanic white	1.08	1.11	1.06	1.12	1.40	1.36	1.41	1.30
Nonwhite	0.88	1.06	0.91	0.95	1.78	1.08**	1.62	1.27
Age (y)								
≤60	1.03	1.02	0.98	1.02	1.46	1.27**	1.52	1.29**
>60	1.10	1.15	1.10	1.13	1.38	1.41	1.38	1.30
Moderate and vigorous activity level (h/wk)								
<7	1.03	1.08	1.10	1.06	1.45	1.23***	1.38	1.26*
≥7	1.12	1.14	1.00	1.16	1.41	1.38	1.46	1.32*
Smoking status								
Never	1.04	1.09	1.01	1.03	1.39	1.24*	1.38	1.25*
Former	1.15	1.16	1.16	1.14	1.44	1.40	1.43	1.34
Current	0.99	1.01	0.95	1.11	1.49	1.26*	1.62	1.24*
Alcohol intake (g/d)								
0	1.02	1.09	1.07	1.08	1.44	1.25**	1.38	1.27
0.3-5.9	1.11	1.14	1.05	1.09	1.27	1.38	1.39	1.30
>6.0	1.12	1.06	1.04	1.13	1.49	1.38	1.48	1.32*
BMI								
<27	1.10	1.18	1.12	1.13	1.52	1.42	1.49	1.35*
≥27	1.02	0.97	0.96	1.04	1.36	1.25*	1.35	1.24*
Supplement use (no./d)								
0	1.04	1.05	0.99	1.04	1.41	1.37	1.34	1.32
1	1.09	1.14	1.16	1.12	1.44	1.32	1.58	1.28**
2+	1.12	1.16	1.06	1.14	1.49	1.34	1.41	1.25**
Weight change from baseline, lb (kg)								
Lost 5+ (2.3)	1.01	1.15	1.02	1.08	1.30	1.35	1.38	1.38
Change less than 5 (2.3)	1.08	1.06	1.13	1.13	1.49	1.37*	1.42	1.27**
Gained 5+ (2.3)	1.06	1.03	0.99	1.04	1.41	1.16*	1.46	1.21**

[a]All statistical analysis done using analysis of variance.
[b]C=control group.
[c]I=intervention group. See Table 1 for definitions of additional terms.
*Significantly different from control, $P<.05$.
**Significantly different from control, $P<.01$.
***Significantly different from control, $P<.001$.

situations, whereas social desirability bias reflects desire to avoid criticism by responding in a way consistent with societal norms or beliefs (40). Several studies have shown that social desirability or social approval bias affect reporting accuracy of men and women on diets (40-42). Hebert and colleagues (40) showed that men scored lower than women in social desirability bias but higher in social approval bias. Social approval bias may be influencing results confined to men in the PPT. The Multiple Risk Factor Intervention Trial, a dietary intervention with all male participants, found that after baseline, intervention men underreported more than control men did (545 kcal compared with 176 kcal) and that these differences in energy could not be explained by weight loss (43). A controlled diet study (44) showed that men, but not women, tended to underreport, but several US studies show a high degree of low EI reporting among women (21,36), perhaps due in part to social desirability bias (40-42). Therefore, assignment to an intervention group may not be associated with any further underreporting by women.

We note study limitations and alternative explanations. The first limitation is the use of the Goldberg cutoff to define low energy reporting. Black (45) reported that assumption of 1.55×BMR for a sedentary lifestyle results in a cutoff value that is too low for all sex and age groups except men and women aged 75 years and older. He concluded that sensitivity for identifying underreporting at the individual level is limited and that information on home, leisure, and occupational activity is essential to assign subjects to low, medium, or high physical activity level before calculating cutoff values (45). This conclusion could explain our finding that less active individuals underreport EI more than their more active counter-

Table 6. Association between EI[a]/BMR[b] and individual demographic and behavioral covariates and intervention status, by sex and study year[c]

	Men				Women			
	Year 1		Year 4		Year 1		Year 4	
	R[d]±SE[e]	*P*	R±SE	*P*	R±SE	*P*	R±SE	*P*
Race								
Non-Hispanic white	−0.02924±0.07210	NS[f]	−0.04032±0.07446	NS	0.01574±0.07545	NS	0.10297±0.08715	NS
Age (y)	−0.00063793±0.00206	NS	−0.0041±0.00211	.05	0.00557±0.00209	.009	0.00347±0.00235	NS
Moderate and vigorous activity (h/wk)	0.00179±0.00156	NS	0.00630±0.00197	.002	0.00456±0.00299	NS	−0.00127±0.00296	NS
BMI[g]	−0.02355±0.00503	.001	−0.01278±0.00501	.01	−0.02116±0.00497	<.0001	−0.01317±0.00498	.009
Intervention Status								
Intervention group	−0.10389±0.03781	.006	−0.14158±0.03799	.002	0.00966±0.04443	NS	0.03544±0.04736	NS

[a]EI=energy intake.
[b]BMR=basal metabolic rate.
[c]Association tested by linear regression analysis.
[d]R=linear regression coefficient.
[e]SE=standard error.
[f]NS=not significant.
[g]BMI=body mass index. See Table 1 for additional term definitions.

parts. Because we did not have detailed information about participant occupational and leisure activity and because self-reported physical activity is often overreported (46), we chose to rely more heavily on estimated EI/BMR.

Another limitation is that the energy expenditure is estimated, not based on more precise methods such as indirect calorimetry or doubly labeled water measurements.

CONCLUSIONS

Self-reported dietary intake measures are used in dietary intervention trials to help monitor compliance, to assist in modifying protocols, to test initial assumptions, and to decide whether adequate study power assumptions exist. Our study and others show that EI underreporting may differ between subgroups of intervention and control participants; therefore, self-reporting measures should be complemented with measures that are not subject to such bias. For example, the PPT collected blood from a sample of participants and assessed biomarkers, serum carotenoid levels and lipid profiles, to measure compliance. The Women's Healthy Eating and Lifestyle Study (47) used serum carotenoid levels to assess compliance with fruit, vegetable, and vegetable juice intake goals. However, biomarkers may not always be available; for example, lipid profiles may detect change in intake of certain types of fat but not change in total fat intake.

The Women's Health Initiative (48) is using performance measures such as compliance with self-monitoring or attendance at group sessions—both of which are related to goal attainment—to target participants in need of more intensive intervention efforts.

As we continue to study the effect of dietary interventions, we must distinguish inappropriate from appropriate use of dietary intake measures, search for new biomarkers for nutrient or food groups of interest and seek new statistical methods to adjust for underreporting.

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